

## **REMARKS**

### **I. STATUS OF THE CLAIMS**

Claims 42-59 were pending at the time of the Action. Claims 56-59 are canceled. Claims 42 is amended. Support for the amendments to claim 42 can be found at least on page 4, lines 10-18; on page 5, lines 8-16; in Example 7 from page 57, line 9 to page 59, line 15; on page 47, lines 24-28; at page 50, lines 1 to 11; at page 24, lines 1-19 and in the claims as originally filed. Claims 60-64 are new. Support for new claim 60 can be found at least from page 21, line 8 to page 22, line 14. Support for new claims 61 can be found at least at page 7, line 3 and in Example 7, page 58, line 12 to line 15 at page 59. Support for new claims 62 can be found at least in Examples 6 and 7, and in particular at page 55, lines 14 and 15. Support for new claim 63 can be found at least in Example 3 and in particular at page 52, lines 7 to 9; and in Figure 3. Support for new claim 64 can be found at least in Example 3 and in particular at page 52, lines 15 to 18; and in Figure 3.

No new matter has been entered by way of the instant amendment. Claims 42-55 and 60-64 are pending and under examination.

### **II. STATEMENT OF SUBSTANCE OF INTERVIEW**

Applicants' representative Charles P. Landrum, Reg. No. 46,855, conducted a telephonic interview with Examiner Kolker on December 10, 2007. Applicants' representative discussed potential claim amendments and the Reckziegel reference, which is of record. No agreement was reached. Applicants' representative encouraged the Examiner to contact him if an amendment could be entered to avoid appeal.

### **III. CLAIMS 56-58 SATISFY THE REQUIREMENTS OF 35 U.S.C. §112**

Claims 56-58 are rejected under 35 U.S.C. §112 as being indefinite. The rejection is moot in light of the pending claims. Withdrawal of all rejections under 35 U.S.C. §112 is respectfully requested.

### **IV. REJECTIONS UNDER 35 USC § 102**

The Action rejects claims 42-47, 49-51, 53-54, and 59 as allegedly anticipated by Reckziegel (1998).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

#### **Claims 42-47, 49-51, 53, and 54 are patentable over Reckziegel**

Claims 42-47, 49-51, 53, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Reckziegel. Applicants traverse.

As stated above, in order to be anticipatory, a reference must teach all of the claim limitations. As acknowledged by the Examiner, "Reckziegel is silent as to what the sequence of the sodium channels actually is." (emphasis added) In fact the words "nucleic acids", "proteins" or "SCN1A" are nowhere to be found in this reference. Claim 42 recites particular sequences that the inventors have shown to be associated with epilepsy. Applicants note that in order to screen for a particular activity one must know what activity is being targeted. Therefore, contacting a composition with an uncharacterized sodium channel composition, much less not knowing the sequence of any particular sodium channel, usurps the purpose of the method.

Furthermore, inactivating all sodium channel activity does not describe identifying a compound that reduces the activity of the SCN1A sodium ion channel, much less a SCN1A sodium channel associated with epilepsy. Thus, clearly, not all the claim limitations are taught by Reckziegel.

The Examiner states “it is reasonable that the tissue samples from Reckziegel comprise the protein of SEQ. ID NO:3...since the sodium channel 1-alpha protein is the main component of the channel (specification, p. 3).” Applicants respectfully suggest that this rejection is based on a suspicion, particularly in light of the fact that the cells characterized in Reckziegel were isolated from patients having temporal lobe epilepsy. The fact that these subjects were suffering from an epileptic condition inherently speaks to a cellular defect of which a lack of sodium channel is reasonable. There is no way to establish with any certainty that the SCN1A is wildtype, mutated, or even expressed in these patients. It should be re-emphasized from Applicants’ response dated August 16, 2007 that the sodium channel family comprises at least 11 members (SCN1A-SCN11A; see for example: [en.wikipedia.org/wiki/Sodium\\_channel](http://en.wikipedia.org/wiki/Sodium_channel) on the worldwide web) any of which attributes sodium channel activity. The fact that the alpha subunit of SCNA are the main component of the sodium channel, cannot and should not be translated into a teaching that a *particular sequence of a particular family member of the SCNA* family is “reasonably” present in a tissue sample. The fact that the tissue used is from **diseased individuals** further increases the uncertainty as to what is present in such a tissue sample.

Nevertheless, in order to advance the prosecution of the instant case, Applicants have amended claim 42 to specify that the recited composition comprises a recombinantly expressed alpha subunit of the SCN1A sodium channel protein, thus further distinguishing the sample composition from that of Reckziegel. Applicants submit that by using recombinantly expressed SCN1A, the protein is not only described by structure, but is also more abundant than in the non-

characterized mixture of Reckziegel. As alluded to above, the Reckziegel extracts could lack SCN1A. There is no way to predict what the extract from the diseased tissue of Reckziegel comprise, in what proportion the sodium channels are comprised in the mixture, and which of the potential sodium channels is or are fully functional, affected by the disease or simply non-functional. The recombinantly expressed and the specific assessment of SCN1A activity is neither taught **nor suggested** by Reckziegel.

Finally, the Examiner also states that "Once the PTO makes a *prima facie* case of inherency, the burdens shift to applicant to distinguish the claimed invention from the prior art". Firstly, Applicants respectfully submit that the PTO has not provided sufficient evidence to make a *prima facie* case of inherency. In any event, Applicants believe that the above-submitted arguments provide convincing evidence of clear distinctions between the alleged inherency of the prior art and the claimed invention. Nevertheless, Applicants wish to stress that in accordance with Oelrich, 666 F. 2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) "When an anticipation is based upon inherency, however, the inherency *must be certain*, i.e., *the inherency may not be established by probabilities or possibilities*" [emphasis added]. Furthermore, in accordance with *Ex parte Cyba*, 155 USPQ 757 "In order that a rejection based upon inherency may be sustained *such inherency must be certain*" [emphasis added]. It follows that Reckziegel lacks in certainty that a functional SCN1A protein was expressed in the diseased tissue sample it uses to prepare the mixture tested.

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. 102(b) in view of Reckziegel be withdrawn.

## **V. REJECTIONS UNDER 35 USC §103**

The Action rejects (a) claims 42-51, 53, 54, and 59 as allegedly being obvious over Reckziegel in view of Hartshorne; (b) claims 42-47, 49-54, and 59 as allegedly being obvious over Reckziegel in view of Kienle; and (c) claims 42-47, 49-51, 53-55, and 59 as allegedly being obvious over Reckziegel in view of Avanzini. Applicants traverse.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

### **A. Claims 42-51, 53, and 54 are patentable over Reckziegel in view of Hartshorne**

Claims 42-51 and 53-54 have been rejected under 35 USC 103 (a) as being unpatentable over Reckziegel in view of Hartshorne. In order “to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03. As set forth above and incorporated here by reference, Reckziegel fails to disclose or suggest a method for the identification of a test compound that modulates SCN1A having the defined sequence. Similarly, while Hartshorne teaches the purification of sodium channels it fails to disclose or suggest a recombinantly expressed SCN1A protein. In addition it is impossible from Hartshorne to know which sodium channel has been purified. Therefore, the combination of Reckziegel and Hartshorne fails to disclose or suggest every element of the claimed invention.

### **B. Claims 42-47 and 49-54 are patentable over Reckziegel in view of Kienle**

Claims 42-47 and 49-54 have been rejected under 35 USC 103 (a) as being unpatentable over Reckziegel in view of Kienle. The combination of Reckziegel and Kienle fail to disclose or

suggest every element of the claimed invention. The defects of Reckziegel are not remedied by Kienle.

**C. Claims 42-47, 49-51, and 53-55 are patentable over Reckziegel in view of Avanzini**

Claims 42-47, 49-51 and 53-55 have been rejected under 35 USC 103(a) as being unpatentable over Reckziegel in view of Avanzini. Avanzini fails to remedy the deficiency of Reckziegel. The combination does not disclose or suggest every element of the claimed invention.

In view of the above, Applicants respectfully request the withdrawal of all obviousness rejections.

**VI. CONCLUSION**

Applicants believe that the present document is a full and complete response to the Action dated October 29, 2007. Applicants request entry of the instant amendment because the amendments place the instant application in condition for allowance, or in the least in better form for appeal.

The Examiner is strongly invited to contact the undersigned Attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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